PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Frederick M. Enright *et al.*

Serial No. 10/617,561

Filing Date: July 11, 2003

Group 1647

Examiner Dang, Ian D.

For: Ligand / Lytic Peptide Compositions and Methods of Use (File 96A3.3 Enright)

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This paper is submitted in response to the May 31, 2006 restriction requirement.

No further amendments are presented.

It is believed that no fee is required to submit this paper. If a fee should be due, please refer to the Deposit Account Authorization previously filed for this application. If any extension of time is required, please consider this paper a petition for the total extension of time required. See 37 C.F.R. § 1.136(a)(3).

Applicants respectfully traverse the restriction requirement, for the reasons given below.

CERTIFICATE

I hereby certify that this Response to Restriction Requirement is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 30, 2006.

John H. Runnels
Registration No. 33,451
June 30, 2006

Provisional Election

In response to the restriction requirement, Applicants provisionally elect with traverse Group I, which the Office identified as including Claims 1-8, 11-14, 17, 127, 129, and 130.

Traversal of Restriction Requirement

There are two separate criteria that must both be satisfied for a restriction requirement to be proper:

(1) The inventions must be independent or distinct as claimed;

and

(2) There must be a serious burden on the examiner if restriction is not required.

M.P.E.P. § 803.

The Office has not shown that either condition is satisfied. Unless both conditions are satisfied, restriction may not be required.

The Office has not established distinctness of the Groups.

The Office has not established that Group I is distinct from any of the other Groups. In each case, the Office said that the method of Group II, III, IV, or V might be practiced with a materially different product. The Office has failed to make such a showing.

The Claims of each of Groups II, III, and IV are drawn to methods of using DNA sequences as recited. The Office's asserted alternatives do not employ such DNA sequences. The Office's asserted alternatives fall outside the scope of the claimed methods, and are therefore irrelevant.

Regarding Group II, the Office asserted that estrogen might be used.

Regarding Group III, the Office asserted that a growth inhibitor agent might be used.

Regarding Group IV, the Office asserted that an antisense might be used.

M.P.E.P. § 806.05(h), in pertinent part, requires a showing that "the process of using ***as claimed*** can be practiced with another materially different product . . . ." (emphasis added)

The alternative methods cited by the Office for Groups II, III, and IV are not examples of the process ***as claimed***. The proposed alternative methods do not employ the recited DNA sequences. Instead, they are examples of completely different processes that are directed to similar ends. The Office has not satisfied its burden of showing that any of the processes ***as claimed*** might be practiced with other products. Instead, the Office has shown that different processes exist for achieving similar goals. But the existence of alternative means to a similar end is irrelevant, if the proposed alternative processes fall outside the scope of the claimed methods.

The Office has fundamentally mischaracterized the Claims of Group V. The Office asserted that "Inventions I and V are related as product and process of use." This statement is clearly incorrect. Each Claim in Group V is directed to a product, not to a process. Accordingly, the Office's argument concerning an alleged alternative process is misplaced.

In summary, the Office has not carried its burden of showing that Group I is distinct from any of Groups II, III, IV, and V. The restriction requirement should be withdrawn.

The Office Has Not Satisfied Its Burden of Showing That There Would be a Serious Burden in Examining the Groups together.

In the alternative, even if the Office had shown that the Groups were distinct from one another (and it has not), restriction would still not be justified, because the Office has not shown that there would be a serious burden in examining the Groups together. "Serious burden" is also a required to justify restriction. See M.P.E.P. § 803.

On an initial point, the Office has acknowledged that Groups II, III, and IV are identically classified, namely, in class 514, subclass 12. Thus the Office has acknowledged that there would be no burden in examining Groups II, III, and IV together.

For this reason alone, at least the restriction requirement among Groups II, III, and IV should be withdrawn.

There is, however, a more fundamental reason why there would be no serious burden in examining all Groups together. This reason was explained in the July 11, 2003 Preliminary Amendment. The following is based largely on that earlier discussion.

It is respectfully submitted that all Claims should be in condition for prompt allowance in light of their close relationship to the Claims that have already been fully examined and allowed in the "parent" case, S.N. 09/381,879, now issued as U.S. patent 6,635,740.

The previously submitted Terminal Disclaimer should fully address any questions that might otherwise be raised concerning double patenting.

As discussed in detail in the Preliminary Amendment, the language of all Claims, except for"new" Claims 129-133, was modeled closely on the language of the issued Claims in the "parent" case, now U.S. patent 6,635,740. A principal difference is that the present Claims refer to DNA that encodes peptides having specified domains, while the issued claims refer to compounds having specified domains. Once the latter has been determined to be patentable, it should follow that the former is patentable as well.

The Office determined that all Claims in the parent case satisfied the requirements of 35 U.S.C. § 112, first paragraph concerning an adequate disclosure. As discussed in greater detail in the Preliminary Amendment, the limitations that were added to the "currently amended" Claims, as well as the limitations in the four "new" Claims, were fully supported by the specification. It therefore follows that the pending Claims all satisfy the requirements of 35 U.S.C. § 112, first paragraph.

The Office determined that all Claims in the parent case satisfied the requirements of 35 U.S.C. § 112, second paragraph concerning definiteness. Since the language of the Claims as allowed in the parent case has been closely followed in the present application, it is believed that the language of the present Claims should likewise be found to be definite. It is also believed that the "new" limitations of the "currently amended" Claims, and all limitations of the "new" Claims should be considered definite as well. If the Examiner should nevertheless identify any minor objections to the Claim language,

objections that might be readily resolved by informal discussion on the telephone, the undersigned would welcome a telephone call from the Examiner to discuss any such objections before a formal action on the merits is prepared.

The Office determined that all Claims in the parent case satisfied the requirements of 35 U.S.C. §§ 102 and 103 concerning novelty and nonobviousness. It logically follows that the Claims in the present case are novel and nonobvious as well. A principal change from the Claims of the parent case to the corresponding pending Claims of the present case was to replace earlier limitations directed to certain peptides with the current limitations directed to DNA sequences encoding those same peptides. If a peptide is novel and nonobvious, then it is almost a logical necessity that a DNA sequence encoding that peptide will be novel and nonobvious as well.

Aside from the principal change described in the preceding paragraph, all other substantive claim amendments were narrowing -- e.g., removing non-peptide hormones from a list of alternative limitations, or adding new dependent Claims with further limitations. If a broader Claim is novel and nonobvious, then it logically follows that the narrower Claim must necessarily be novel and nonobvious as well.

It is respectfully submitted that all pending claims are patentable, in view of their close relationship to the allowed Claims in the parent case.

Further, in view of the close relationship between the subject matter of the pending Claims and the subject matter of the allowed Claims, it is respectfully submitted that the examination of all pending Claims will not present a serious burden to the Office. To a large extent, that subject matter was already examined in the parent case, now U.S. patent 6,635,740.

Conclusion

The restriction requirement should be withdrawn, and all Claims should be examined on their merits.

The Examiner is respectfully advised that if the restriction requirement should be repeated, then it is the Applicants' present intention to file a formal Petition to review the propriety of the restriction requirement.

Allowance of all Claims at an early date is respectfully requested.

Respectfully submitted,

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